

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF TEXAS  
LUFKIN DIVISION**

**SANOFI-AVENTIS  
DEUTSCHLAND GMBH,**

Plaintiff,

**VS.**

GENENTECH, INC. and  
BIOGEN IDEC INC.,

Defendants.

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Case No. \_\_\_\_\_

## TRIAL BY JURY DEMANDED

## COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Sanofi-Aventis Deutschland GmbH (“SANOFI-AVENTIS”) hereby complains of Defendants, Genentech, Inc. (“GENENTECH”) and Biogen Idec Inc. (“BIOGEN”), as follows:

## PARTIES

1. SANOFI-AVENTIS is a corporation organized and existing under the laws of Germany, with offices located at Brüningstrasse 50, D-65929 Frankfurt am Main, Germany.

2. On information and belief, GENENTECH is a corporation organized and existing under the laws of the State of Delaware, with offices located at 1 DNA Way, South San Francisco, California.

3. On information and belief, BIOGEN is a corporation organized and existing under the laws of the State of Delaware, with offices located at 14 Cambridge Center, Cambridge, Massachusetts.

**JURISDICTION AND VENUE**

4. The present action alleges infringement of two United States Patents under 35 U.S.C. § 271, including at least § 271(a), § 271(b) and § 271(g).

5. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

6. This Court has personal jurisdiction over GENENTECH and BIOGEN. GENENTECH and BIOGEN have purposefully and voluntarily placed their products, including infringing products, into the stream of commerce with the expectation that these products will be purchased by consumers in this judicial district. GENENTECH and BIOGEN have done so as part of their continuous and systematic general business contacts with this judicial district. These products, including infringing products, have been and continue to be purchased by consumers in this judicial district.

7. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400.

**FACTS**

8. SANOFI-AVENTIS is a leading international pharmaceutical company that strives to meet a wide array of healthcare needs through innovative products. SANOFI-AVENTIS's extensive research and development efforts are focused on health care challenges in cardiology, oncology and internal medicine, as well as metabolic diseases, central nervous system disorders and vaccines.

9. SANOFI-AVENTIS is the owner of all right, title and interest in and to U.S. Patent No. 5,849,522 ("the '522 Patent"), which issued on December 15, 1998 and U.S. Patent

No. 6,218,140 (“the ‘140 Patent”), which issued on April 17, 2001. The ‘522 Patent and the ‘140 Patent both pertain to, among other things, nucleic acid enhancers for cellular expression systems useful for producing drugs and antibodies for human therapy. A true and correct copy of the ‘522 Patent is attached hereto as Exhibit 1 and a true and correct copy of the ‘140 Patent is attached hereto as Exhibit 2.

10. On August 6, 1992, representatives of GENENTECH and Behringwerke AG, Postfach 11 40, 3550 Marburg, Federal Republic of Germany, entered into a license agreement with an effective date of January 1, 1991 (“the License Agreement”). Under the License Agreement, Behringwerke AG granted to GENENTECH a nonexclusive license to, *inter alia*, the ‘522 Patent and the ‘140 Patent. By virtue of a series of assignments, SANOFI-AVENTIS became the owner of all right, title and interest in and to the ‘522 Patent and the ‘140 Patent. SANOFI-AVENTIS is also the successor in interest to Behringwerke AG such that SANOFI-AVENTIS stands in the shoes of Behringwerke AG for the purposes of the License Agreement. In a letter dated August 27, 2008, GENENTECH provided SANOFI-AVENTIS with notice of termination of the License Agreement, the termination to be effective on October 27, 2008.

11. On information and belief, GENENTECH is a healthcare company with locations in the United States that uses human genetic information to manufacture and commercialize biotherapeutics.

12. On information and belief, GENENTECH manufactures and/or commercializes multiple biotherapeutics for medical conditions in the areas of oncology, immunology and disorders of tissue growth and repair, including but not limited to Avastin® (bevacizumab), Herceptin® (trastuzumab), Rituxan® (rituximab), Raptiva® (efalizumab), Xolair® (omalizumab), Activase® (alteplase), Cathflo® Activase® (alteplase), Pulmozyme® (dornase

alfa) and TNKase® (tenecteplase). On information and belief, GENENTECH has manufactured, used, offered for sale and/or sold each of these products in the United States, including within this judicial district.

13. On information and belief, BIOGEN is a healthcare company with locations in the United States that uses human genetic information to manufacture and commercialize biotherapeutics.

14. On information and belief, BIOGEN manufactures and/or commercializes multiple biotherapeutics for medical conditions in the areas of oncology, immunology and nuerology, including but not limited to Avonex® (interferon beta-1a), Rituxan® (rituximab), Tysabri® (natalizumab) and Fumaderm® (dimethylfumarate and monoethylfumarate salts). On information and belief, BIOGEN has manufactured, used, offered for sale and/or sold each of these products in the United States, including within this judicial district.

15. On information and belief, GENENTECH and BIOGEN are commercialization partners with respect to Rituxan® (rituximab).

## **PATENT INFRINGEMENT**

### **COUNT I**

16. SANOFI-AVENTIS incorporates herein by this reference the allegations of paragraphs 1 through 15.

17. On information and belief, GENENTECH and BIOGEN are infringing and will continue to infringe the '522 Patent by making, using, selling and/or offering for sale in the United States, including within this judicial district, certain biotherapeutics made in the United States in mammalian cell suspension cultures utilizing the invention claimed in one or more

claims of the '522 Patent, including but not limited to Avastin® (bevacizumab), Herceptin® (trastuzumab), Rituxan® (rituximab), Raptiva® (efalizumab), Xolair® (omalizumib), Activase® (alteplase), Cathflo® Activase® (alteplase), Pulmozyme® (dornase alfa) and TNKase® (tenecteplase).

18. As a result of the infringement by GENENTECH and BIOGEN, SANOFI-AVENTIS is being and continues to be irreparably harmed.

19. GENENTECH and BIOGEN were well aware of the '522 Patent prior to the commission of the infringing acts alleged herein, including by having licensed rights under the '522 Patent, then terminated the license. Infringement of the '522 Patent by GENENTECH and BIOGEN is and will continue to be reckless, egregious and willful.

20. SANOFI-AVENTIS has no adequate remedy at law.

21. On information and belief, GENENTECH and BIOGEN will continue their infringing activities, and continue to damage SANOFI-AVENTIS, unless enjoined by this Court. SANOFI-AVENTIS's damages from the aforesaid actions of GENENTECH and BIOGEN are not yet determined.

22. GENENTECH and BIOGEN's reckless, egregious and willful infringement of the '522 Patent makes this an exceptional case under 35 U.S.C. § 285.

## **COUNT II**

23. SANOFI-AVENTIS incorporates herein by this reference the allegations of paragraphs 1 through 15.

24. On information and belief, GENENTECH and BIOGEN are infringing and will continue to infringe the '140 Patent by making, using, selling and/or offering for sale in the United States, including within this judicial district, certain biotherapeutics made in the United

States in mammalian cell suspension cultures utilizing the invention claimed in one or more claims of the '140 Patent, including but not limited to Avastin® (bevacizumab), Herceptin® (trastuzumab), Rituxan® (rituximab), Raptiva® (efalizumab), Xolair® (omalizumib), Activase® (alteplase), Cathflo® Activase® (alteplase), Pulmozyme® (dornase alfa) and TNKase® (tenecteplase).

25. As a result of the infringement by GENENTECH and BIOGEN, SANOFI-AVENTIS is being and will continue to be irreparably harmed.

26. GENENTECH and BIOGEN were well aware of the '140 Patent prior to the commission of the infringing acts alleged herein, including by having licensed rights under the '140 Patent, then terminated the license. Infringement of the '140 Patent by GENENTECH and BIOGEN is and will continue to be reckless, egregious and willful.

27. SANOFI-AVENTIS has no adequate remedy at law.

28. On information and belief, GENENTECH and BIOGEN will continue their infringing activities, and continue to damage SANOFI-AVENTIS, unless enjoined by this Court. SANOFI-AVENTIS's damages from the aforesaid actions of GENENTECH and BIOGEN are not yet determined.

29. GENENTECH and BIOGEN's reckless, egregious and willful infringement of the '140 Patent makes this an exceptional case under 35 U.S.C. § 285.

### **DECLARATORY JUDGMENT**

#### **COUNT III**

30. SANOFI-AVENTIS incorporates herein by this reference the allegations of paragraphs 1 through 15.

31. On information and belief, GENENTECH and BIOGEN are infringing and will continue to infringe the '522 Patent by making, using, selling and/or offering for sale in the United States, including within this judicial district, certain biotherapeutics which were made in the United States in mammalian cell suspension cultures utilizing the invention claimed in one or more claims of the '522 Patent, including but not limited to Avastin® (bevacizumab), Herceptin® (trastuzumab), Rituxan® (rituximab), Raptiva® (efalizumab), Xolair® (omalizumib), Activase® (alteplase), Cathflo® Activase® (alteplase), Pulmozyme® (dornase alfa) and TNKase® (tenecteplase).

32. GENENTECH and BIOGEN's activities related to the making, using, selling and/or offering for sale certain biotherapeutics, including but not limited to Avastin® (bevacizumab), Herceptin® (trastuzumab), Rituxan® (rituximab), Raptiva® (efalizumab), Xolair® (omalizumib), Activase® (alteplase), Cathflo® Activase® (alteplase), Pulmozyme® (dornase alfa) and TNKase® (tenecteplase), constitute infringement of the '522 Patent under 35 U.S.C. § 271.

33. There is an ongoing and justiciable case and controversy based on GENENTECH and BIOGEN's infringement of the '522 Patent. SANOFI-AVENTIS is entitled to a declaratory judgment that GENENTECH and BIOGEN infringe or will infringe one or more claims of the '522 Patent.

#### **COUNT IV**

34. SANOFI-AVENTIS incorporates herein by this reference the allegations of paragraphs 1 through 15.

35. On information and belief, GENENTECH and BIOGEN are infringing and continue to infringe the '140 Patent by making, using, selling and/or offering for sale in the

United States, including within this judicial district, certain biotherapeutics which were made in the United States in mammalian cell suspension cultures utilizing the invention claimed in one or more claims of the '140 Patent, including but not limited to Avastin® (bevacizumab), Herceptin® (trastuzumab), Rituxan® (rituximab), Raptiva® (efalizumab), Xolair® (omalizumib), Activase® (alteplase), Cathflo® Activase® (alteplase), Pulmozyme® (dornase alfa) and TNKase® (tenecteplase).

36. GENENTECH and BIOGEN's activities related to the making of certain biotherapeutics, including but not limited to Avastin® (bevacizumab), Herceptin® (trastuzumab), Rituxan® (rituximab), Raptiva® (efalizumab), Xolair® (omalizumib), Activase® (alteplase), Cathflo® Activase® (alteplase), Pulmozyme® (dornase alfa) and TNKase® (tenecteplase), constitute infringement of the '140 Patent under 35 U.S.C. § 271.

37. There is an ongoing and justiciable case and controversy based on GENENTECH and BIOGEN's infringement of the '140 Patent. SANOFI-AVENTIS is entitled to a declaratory judgment that GENENTECH and BIOGEN infringe or will infringe one or more claims of the '140 Patent.

**WHEREFORE**, SANOFI-AVENTIS prays for judgment that:

A. Determines and declares that GENENTECH and BIOGEN have infringed claims of the '522 Patent;

B. GENENTECH and BIOGEN, their officers, agents, servants and employees, and those persons in active concert and participation with any of them, be preliminarily and permanently enjoined from further infringement of the '522 Patent;



C. Determines and declares that GENENTECH and BIOGEN have infringed claims of the '140 Patent;

D. GENENTECH and BIOGEN, their officers, agents, servants and employees, and those persons in active concert and participation with any of them, be preliminarily and permanently enjoined from further infringement of the '140 Patent;

E. SANOFI-AVENTIS be awarded damages sufficient to compensate it for the infringement, but in no event less than a reasonable royalty for such infringement, and that such damages be increased to three times the amount found or assessed pursuant to 35 U.S.C. § 284, together with prejudgment interest;

F. This case be declared exceptional pursuant to 35 U.S.C. § 285 and that SANOFI-AVENTIS be awarded its attorney's fees, costs and expenses in this action; and

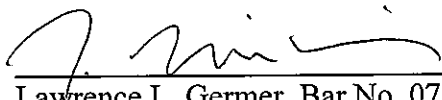
G. SANOFI-AVENTIS be awarded such other and further relief as the Court may deem just.

**DEMAND FOR JURY TRIAL**

SANOFI-AVENTIS hereby demands a jury trial on all issues.

Respectfully submitted,

Date: October 27, 2008



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